

Rec'd PCT/PTO 16 MAR 2005

PATENT COOPERATION TREATY

REC'D 22 DEC 2004

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# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference BES 0009 PB	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IB 03/04070	International filing date (day/month/year) 18.09.2003	Priority date (day/month/year) 19.09.2002
International Patent Classification (IPC) or both national classification and IPC A61F2/01		
Applicant BESSELINK, Petrus		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.  
  
☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
 These annexes consist of a total of 4 sheets.

- This report contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand 12.04.2004	Date of completion of this report 23.12.2004
Name and mailing address of the International preliminary examining authority:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Mary, C  Telephone No. +31 70 340-4409  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/IB 03/04070

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-49 as originally filed

**Claims, Numbers**

1-74 as originally filed

**Drawings, Sheets**

1/20-20/20 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
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International application No. **PCT/B 03/04070**

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**Y Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**Statement**

Novelty (N)	Yes: Claims	1-74
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-74
Industrial applicability (IA)	Yes: Claims	1-74
	No: Claims	

2. Citations and explanations  
**see separate sheet**

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EXAMINATION REPORT - SEPARATE SHEET**

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**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: EP-A-1 226 795 (PAVLOVIC JENNIFER L) 31 July 2002 (2002-07-31)

D2: US5836962 (GIANOTTI MARC) 17 November 1998 (1998-11-17)

The document D2 was not cited in the international search report. A copy of the document is appended hereto.

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-74 does not involve an inventive step in the sense of Article 33(3) PCT.

The document **D1** is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document) (see paragraphs 44 to 71): a medical device (10) configured to be disposed within a body lumen, said device comprising reinforcement fibers (14).

The subject-matter of claim 1 therefore differs from this known medical device in that the medical device comprises a membrane, the reinforcement fibers being coupled to the membrane.

The problem to be solved by the present invention may therefore be regarded as improving the strength and flexibility of the medical device.

The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons. Embedding fibers into a membrane is described in document D2 (see column 6, line 46 to column 7, line 46) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the medical device described in document D1 in order to solve the problem posed.

3. The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 48, 53, 55, 61, which therefore are also considered not inventive.

4. Dependent claims 2-47, 49-52, 54, 56-60, 62-74 do not contain any features which,

**INTERNATIONAL PRELIMINARY  
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in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see documents D1 and D2.

**Remarks:**

**5.** The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

## INTERNATIONAL SEARCH REPORT

Internat. Application No  
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A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

## DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 226 795 A (PAVLOVIC JENNIFER L) 31 July 2002 (2002-07-31) paragraph '0044! - paragraph '0071!	1-60
A	---	61-74
X	US 6 171 338 B1 (TOERMAELAE PERTTI ET AL) 9 January 2001 (2001-01-09) column 3, line 51 -column 12, line 49	1,2, 61-74
X	US 5 024 671 A (MATHEWSON WILFRED F ET AL) 18 June 1991 (1991-06-18) column 3, line 59 -column 7, line 33	1 2-74
X	US 6 001 100 A (TOERMAELAE PERTTI ET AL) 14 December 1999 (1999-12-14) column 4, line 24 -column 5, line 7	1,61-74
A	---	2-60
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

14 January 2004

Date of mailing of the international search report

21/01/2004

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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/1003/04070

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 2003/023265 A1 (FORBER SIMON JOHN) 30 January 2003 (2003-01-30) paragraph '0041! - paragraph '0115! -----	1-13, 15-58
A	WO 01 30267 A (ATRITECH INC) 3 May 2001 (2001-05-03) the whole document -----	1-74
A	WO 99 44510 A (BIOGUIDE CONSULTING INC ;SISSKIND STEVEN J (US); VU DAC (US)) 10 September 1999 (1999-09-10) page 7, line 12 -page 11, line 3 -----	1-74

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International Application No

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EP 1226795	A	31-07-2002	US 2002128680 A1 12-09-2002
		CA 2369887 A1 25-07-2002	
		EP 1226795 A2 31-07-2002	
		JP 2002355247 A 10-12-2002	
US 6171338	B1	09-01-2001	FI 885164 A 11-05-1990
		US 5792400 A 11-08-1998	
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		AT 136796 T 15-05-1996	
		AU 636311 B2 29-04-1993	
		AU 4503289 A 28-05-1990	
		CA 2010274 A1 16-08-1991	
		DE 68926305 D1 23-05-1996	
		DE 68926305 T2 05-12-1996	
		EP 0442911 A1 28-08-1991	
		WO 9004982 A1 17-05-1990	
		JP 2931004 B2 09-08-1999	
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		EP 1225843 A1 31-07-2002	
		JP 2003529410 T 07-10-2003	
		JP 2003512128 T 02-04-2003	
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		WO 0130266 A1 03-05-2001	
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		WO 0130268 A1 03-05-2001	
		US 2003120337 A1 26-06-2003	
		US 2003191526 A1 09-10-2003	
		US 6652556 B1 25-11-2003	
WO 9944510	A	10-09-1999	AU 2994499 A 20-09-1999
		EP 1061856 A1 27-12-2000	



## INTERNATIONAL SEARCH REPORT

Internal Application No  
PCT/1993/04070

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9944510 A		WO 9944510 A1	10-09-1999